

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 13, 24, 30, 34, 49 and 51 are currently being amended. Claims 1, 13, 24, 30, 34 are being amended to add further limitation that the bag for use in the centrifugal processor is a "flexible" bag. Support for amendments to these claims can be found throughout the original application, and at least on page 6, at lines 12-13.

Claim 49 is being amended to add further limitation that it is a "portion of an" exterior surface of the first side "adjacent to the first mating portion" that is flat. Support for amended claim 49 can also be found throughout the original application, and at least at FIG. 2C.

Claim 51 is being amended to restructure it as a markush group and to remove "any combinations thereof." Support for amended claim 51 can be found throughout the original application, and at least at the bottom of page 7. No new matter is added by way of any of these amendments.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-6, 8-18, 20-30 and 32-51 are now pending in this application, of which claims 39-48 have been previously withdrawn from consideration.

Rejections under 35 U.S.C. §112

Claim 49 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Claim 49 as amended herein describes that portion of an exterior surface adjacent to the first mating portion being flat. Support can be found at least in the illustration of FIG. 2C showing a cross sectional view of the processor/expressor chamber with detail of the first and second sides adjacent to the axial opening. Raised areas are illustrated along interior surfaces adjacent to the axial opening. That portion of the exterior surface adjacent to the mating portion is illustrated by a straight line, indicating that in the exemplary embodiment, that portion of the exterior surface is substantially flat.

Claim 51 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Applicants submit that the objection is moot in view of amendments made to claim 51 herein.

Rejections under 35 U.S.C. §102

Claims 1-6, 8-18, 20-29, 34, 49, and 51 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Published Patent App. No. 2002/0107131 to Jorgensen et al. (Jorgensen et al.). Applicants respectfully traverse for reasons set forth below.

Applicants submit that the rejection is improper because Jorgensen et al. fails to disclose, teach or suggest each and every element of Applicants' claims. (See MPEP §2131.) Independent claim 1, as amended, recites:

A flexible bag for use in centrifugal processing comprising:

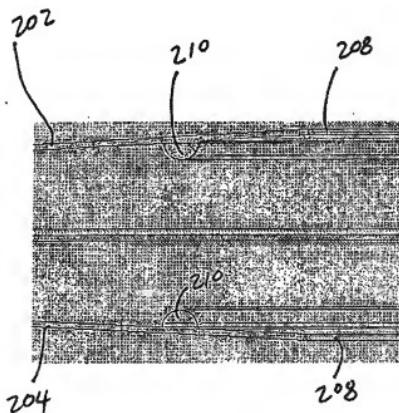
a substantially circular enclosure including a first side and a second side radially connected to the first side along an outer edge, the first and second sides defining an interior surface therebetween, the first and second sides each having a respective central opening for housing a central hub; and

a first mating portion positioned adjacent to the central opening, along the interior surface of the first side extending in a direction perpendicular to the interior surface, and, in cross-section, including at least one of a raised or recessed

shape with respect to the interior surface, the first mating portion integrally formed for mating in a cooperative arrangement with a corresponding mating portion of the central hub, and the raised or recessed shape of the first mating portion opposing an interior surface of the second side.

In particular, independent claim 1, as amended, recites "a flexible bag" comprising among other features "a first mating portion." Thus, the first mating portion recited in Applicants' claims is part of the flexible bag. More particularly, the first mating portion, which is part of the flexible bag, is claimed as being "integrally formed." Independent claims 13 and 24 recite similar limitations.

For example, although it is to be understood that the scope of the claims is not limited to the specific examples found in the specification, Applicants' Figure 2C reproduced below shows a processor or expressor bag 200 featuring circumferential raised portions 210 along an interior surface that surround the axial opening 208.



Applicants respectfully submit that Jorgensen et al. does not disclose, teach, or suggest “a first mating portion positioned adjacent to the central opening” is a component of the flexible bag, and that the “the first mating portion is integrally formed.”

The Office Action appears to rely upon weld rings 100 described in Jorgensen et al. at ¶0043 and illustrated in FIG. 11, as corresponding to Applicants’ claimed first mating portion. The particular embodiment of Jorgensen et al. relied upon in the Examiner’s rejection describes a bag within a bag *assembly* 94. (Jorgensen et al., ¶0050). Jorgensen et al. describes that “[e]ach processing or expressor *bag* is comprised of a flexible compartment, a central hub and weld rings for connecting the flexible compartment to the central hub. (Id., ¶0043, emphasis added). Although the weld rings are described as being part of Jorgensen et al.’s “*bag*” *assembly* they are not described as being part of the “flexible compartment” itself. To the contrary, as illustrated FIG. 12, showing an exploded perspective view of a processor bag within a bag embodiment (i.e., assembly), the weld rings 100 are illustrated as *separate* components from either processing bag 96, 98. They may be part of the assembly, but they are not part of the flexible compartment. Thus, the weld rings are not integral to either of the expressor or processing chambers. Rather, the weld rings are separate and part of an assembly that also includes the hub. (Id., see for example, ¶0047).

Whereas “the processing chambers and expressor chambers are constructed from two sheets of *flexible* material, the two sheets of material sealed at an outer circumference and an inner circumference” (Id., ¶0014, emphasis added), the weld rings are described as being “constructed using a *rigid* plastic material.” (Id., ¶0043). As further evidence that the weld rings are not an integrally formed part of the flexible chamber, the weld rings are described as being constructed of different material than the flexible chambers (i.e., flexible material versus rigid plastic material).

Accordingly, the rejection of independent claims 1, 13, and 24 as anticipated by Jorgensen et al. is without proper basis. Dependent claims 2-6, 8-18, 20-29, 49, and 51 depend, directly or indirectly, from respective ones of independent claims 1, 13, and 24 and thus

distinguish Jorgensen et al. for at least the same reasons. Independent claim 34 also recites similar limitations and thus distinguishes Jorgensen et al. for at least the same reasons set forth above. Applicants therefore respectfully request reconsideration and withdrawal of the rejection of these claims.

Rejections under 35 U.S.C. §103

Claims 35-38 are rejected under 35 U.S.C. §103(a) as being unpatentable over Jorgensen et al. Applicants respectfully traverse for reasons set forth below.

Applicants respectfully submit that Jorgensen et al. fails to teach or suggest each and every element of the rejected claims.

Dependent claims 35 and 38 each depend from independent claim 34, which as amended recites similar limitations to those discussed above in distinguishing Jorgensen et al. Namely, claim 34 recites “a flexible bag” comprising a central opening including “a first mating portion positioned adjacent to the central opening, along the interior surface of the first side,” wherein “the first mating portion is integrally formed.” Thus, even if the discussion of “weld rings” in Jorgensen et al. would have suggested welding, either with heat or with solvent, as noted above, Jorgensen et al. fails to disclose, teach or suggest each and every element of the claimed process.

In view of this, Applicants submit that dependent claims 35 and 38 patentably distinguish Jorgensen et al. Applicants therefore respectfully request reconsideration and withdrawal of the rejection of these claims.

Claims 30, 32 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Jorgensen et al. in view of U.S. Patent No. 3,982,691 to Schultz (Schultz). Applicants respectfully traverse for reasons set forth below.

Initially, Applicants do not concede that any of the proposed combinations would have been obvious to one skilled in the art at the time of the invention. However, even assuming

arguendo that the proposed combinations are proper, Applicants respectfully submit that they would still fail to teach or suggest each and every element of the rejected claims.

Independent claim 30, as amended, recites similar limitations to those discussed above in distinguishing Jorgensen et al. Namely, claim 30 recites “a flexible bag” comprising a central opening including “a first mating portion positioned adjacent to the central opening, along the interior surface of the first side,” wherein “the first mating portion is integrally formed.” The Office Action correctly observes that Jorgensen et al. does not explicitly disclose using an adhesive for joining components of a centrifuge bag assembly and relies upon Shultz for this proposition. Shultz fails to cure the deficiencies noted above with respect to Jorgensen et al. Accordingly, the combination of Jorgensen et al. and Shultz fails to disclose, teach or suggest each and every element of the claimed process.

In view of this, Applicants submit that independent claim 30 patentably distinguishes Jorgensen et al. either alone or in combination with the secondary reference. Claims 32 and 33 each depend, directly or indirectly, from independent claim 30, and therefore distinguish Jorgensen et al. for at least the same reasons. Applicants therefore respectfully request reconsideration and withdrawal of the rejection of these claims.

Claim 50 is rejected under 35 U.S.C. §103(a) as being unpatentable over Jorgensen et al.
Applicants respectfully traverse for reasons set forth below.

Applicants respectfully submit that Jorgensen et al. fails to teach or suggest each and every element of the rejected claim.

Dependent claim 50 depends from independent claim 1, which as amended recites limitations discussed above in distinguishing Jorgensen et al. Namely, claim 1 recites “a flexible bag” comprising a central opening including “a first mating portion positioned adjacent to the central opening, along the interior surface of the first side,” wherein “the first mating portion is integrally formed.” Thus, even if even if one of ordinary skill in the art would recognize the shape being semi-circular, as noted above, Jorgensen et al. fails to disclose, teach or suggest each and every element of the claimed structure.

In view of this, Applicants submit that dependent claims 50 patentably distinguish Jorgensen et al. Applicants therefore respectfully request reconsideration and withdrawal of the rejection of this claim.

Applicants believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date July 13, 2009

By



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